

The Maryland Board of Pharmacy Draft Public Minutes - March 17, 1999

President Stanton Ades called the public meeting to order at 8:37 A.M.

Also in attendance were Commissioners W. Irving Lottier, Secretary, Wayne Dyke, Melvin Rubin, Donald Yee, Ramona McCarthy Hawkins, Laura Schneider, Jeanne Gilligan Furman and Raymond Love; Board Counsel, Paul Ballard; Board Staff, David Denoyer, Wendy Wilson and Julie Smith (student).

Guests present: Pharmacists Howard Schiff, Dorothy Levi, and Cathy Putz.

President Ades requested that any member of the Board with a conflict of interest relating to an item on the agenda should notify the Board at this time.

There were no conflicts reported.

Approval of Minutes -

Approval of the minutes was deferred until after lunch. The minutes were subsequently approved with the correction of changing “quest” on page 1 last line to “guest” and on motion by Ramona McCarthy Hawkins, seconded by Laura Schneider.

Executive Director's Report -

President Ades introduced a revised committee and task force membership roster. Ramona McCarthy Hawkins moved to accept the membership of board committees and task forces as listed in the roster as packet item 3a. The motion was seconded by Ray Love and approved by the Board.

Mr. Schiff reported that the Committee headed by George Voxakis has met and is in the process of approaching Med Chi to discuss future of pharmacy practice issues.

With regard to legislative positions, Pam Wiggin reported that Commissioner Rubin had testified before House and Senate Committees on HJR16/SJR5 supporting the resolutions and requesting the participation of a pharmacist member of the Board of Pharmacy in the proposed Task Force on Confidentiality. The Senate Committee appeared more receptive to this suggestion, while the House appeared to prefer a consultative relationship with various professions, rather than the appointment of a pharmacist.

Ms. Wiggin reported on SB586 - which provides some technical refinements to the Pharmacy Practice Act. She mentioned that lobbyists for NACDS had made comments about changes to the definitions of “pharmacy” and “prescription area”. The NACDS representative suggested

The Maryland Board of Pharmacy Draft Public Minutes - March 17, 1999

changing the “and” in line 6 to “or” because of a concern about non-prescription drugs being included in the definition. Board members discussed the issue of storage of prescription records off-site and how the new definition would relate to the storage. The consensus was that the new bill would not prohibit the storage of records off-site.

Commissioner Love commented that the changes are needed to implement and clarify the laws and regulations which apply to pharmacy security and moved the Bill be accepted as written, seconded by Laura Schneider. The motion was approved by the Board. The Board requested that Pamm Wiggin communicate this decision to Senator Hollinger and the lobbyists in writing.

The Board was advised that the April meeting would be held at PG County’s Health Department in Largo, MD. Maps would be faxed to the board members in the next few days.

Mr. Rubin reported to the Board that attempts were in progress to obtain emergency status for an Administrative Officer III position for inclusion in the 2000 budget. He advised the Board that this position was needed to permit Ms. Banks to focus on Y2K issues and other computer requirements and changes in the Board. Ms. Furman and others expressed frustration that an outside consultant could not be hired. Mr. Ades advised those concerned that it would likely take longer to obtain a consultant than add an additional position to the Board’s staff. The matter was referred to Ms. Pease and Ms. Banks to report back to the Board at the April Meeting. Mr. Rubin reported that he is looking into a disciplinary data base and will report at a later Board meeting.

Guest Presenter - There was no guest presenter. Mr. Ades reported that he had spoken with Mr. Steve Cohen regarding his request for a “hospital permit” for the Medstar Infusion Pharmacy in order to obtain hospital discounts for the Medstar pharmacy which will only service hospitals. The status requested is not addressed in the current application which results in a pharmacy or a pharmacy with a waiver, but not a “hospital” permit. The Peer Review Committee was asked to interview Mr. Cohen and report back to the Board regarding his current application and the business plan and how this would relate to outsourcing of pharmacy services. Mr. Ades commented that the request for a specialty license may be outside of the Board’s purview, and noted that the relief sought by Mr. Cohen would be better addressed by the Division of Drug Control and the DEA. Dr. Love commented that this issue may be tied into the “outsourcing” issue that the Practice Committee is addressing.

Board Counsel’s Report - Board Counsel had nothing to report at this time.

Committee Reports

Licensing Committee - Commissioner Wayne Dyke reported that there were 16 reciprocity

The Maryland Board of Pharmacy Draft Public Minutes - March 17, 1999

candidates. The candidates are Wasim Amir, Brian Bernard, Deborah Conway, Sandra Loheide, Michael Misocky, Chinyelu Onwumbiko, Shelley Pszczola, Julianne Shank, Sammy Welashey, Arletta Yahnke. A motion was made by Mr. Lottier and seconded by Ms. McCarthy Hawkins to accept all the candidates for licensure with the exception of four persons who need to pass the oral competency examination, i.e. Julianne Shank, Wasim Amir, Deborah Conway, Arletta Yahnke, who are to be approved pending their passage of the oral competency examination. The Board approved the motion.

Administration of Future Examinations - Wayne Dyke reported on a March 12 1999 meeting with MPHA, and faculty and student representatives from the University of Maryland, School of Pharmacy and Howard University regarding the appropriate timing and sites of examinations. The laboratory examination will be held on Tuesday, June 22 and Wednesday, June 23, 1999 and then quarterly, thereby avoiding late results. Students applying to take this examination would be advised by letter of the scope and objectives of the exam and the grading procedures. Mr Denoyer offered to assist Mr. Dyke in the drafting of the letter.

Mr. Dyke reported that both Howard and Maryland Universities agreed that they could provide adequate notification to the Board in the form of a list of students or a letter indicating a student would be graduating in order to facilitate earlier exams. Both institutions also agreed to provide the Board with reports that students had satisfactorily completed the requirements for graduation as a necessary prerequisite to the students receiving their licenses to practice pharmacy.

Mr. Dyke reported that the site for the law examination by Cogent Inc. are in Towson, Maryland and Fairfax, Virginia. Cogent will be able to test on a continuous basis and may start on about May 7, 1999. The NAPLEX is open monthly at Sylvan Learning Center.

Board members commented that sample lab test questions should be made available and that tall applicants would be notified of the type of problems on the examinations. A discussion of the clinical aspects of the lab exam ensued.

Executive Committee for the Future of Pharmacy Practice - Dr. Voxakis, Chair

Mr. Schiff reported that he had nothing of substance to report from the Future of Pharmacy Practice Committee. Mr. Ades reported that George Voxakis had spoken with Norene Pease and said he would provide minutes to the Board.

Regulation Update

Code of Conduct - Ms. Wiggin reported that the proposed Code of Conduct was published in the Maryland Register of February 12, 1999. To date, two sets of comments have been received

The Maryland Board of Pharmacy Draft Public Minutes - March 17, 1999

by Ms. Phinney at DHMH and forwarded to the Board. Review of the Code in light of these comments and formulation of an appropriate response to PhRMA and NACDS, the two organizations concerned, was referred to the Practice Committee.

Portable Drug Kits - Ms. Wiggin reported that the changes requested by the Board at the February meeting had been completed and a NORD form had been sent downtown to DHMH. The Nursing Board has approved the proposed regulations. Copies of the proposed regulations have been provided to Licensing and Certification who did not expect to be able to consider them until after the close of the legislative session. Meanwhile, final technical revisions are being completed and the regulations will be sent downtown for review and subsequent publication in the very near future. Ms. Wiggin reported a recent meeting with various home-health nurses and their request to be able to carry non-patient specific bottles of saline and H₂O for irrigation purposes only. Dr Love indicated that these nurses would be free to have portable kits consisting only of these products. The issue was considered to be primarily one of relabelling by the manufacturers and this was not likely, given the complexity of the warning required for these legend drugs.

Pharmacy Security - The Board was advised by Ms. Wiggin that these regulations were undergoing final technical requirements and would be sent downtown in the very near future to receive feedback from Ms. Phinney.

BPQA regulations on medical assistants was discussed and Ms. Wiggin suggests that the Board member attend the medical practice subcommittee this Thursday (March 18) at 4 pm to express the Board's concern that a physician be present to dispense.

Mr. Freedman from Drug Control commented that a physician should be present when sample drugs are dispensed.

Executive Committee Meeting with the University of Maryland, School of Pharmacy - The contents of this meeting were discussed under the Licensing Committee Report.

PEAC (Pharmacists Education and Assistance Committee) - Mr. Rubin reported that he would be attending a meeting on March 18 to discuss several pending cases. Mr Denoyer stated that he would also attend the meeting.

Mr. Rubin also reported that only two bids had been received for the RFP, from Shepard Pratt and PEAC. The closing date is March 19 1999. A meeting to review the bids would be held on Tuesday, March 23d. Ms. Furman agreed to provide additional Board review with Mr. Rubin.

Pharmacy Practice Committee

The Maryland Board of Pharmacy Draft Public Minutes - March 17, 1999

Dr. Love reported on the meeting and deferred to the task force chairs for reports as follows:

Task Force on Pharmacy Support Staff - Mr. Rubin had nothing new to report and commented that a draft regulation may be ready by next month. The next Task Force Meeting is 8 a.m. April 8, 1999 at 4201 Patterson Avenue in Baltimore.

Drug Formulary Advisory Committee - Laura Schneider reported that Secretary Wasserman has not appointed an advisory committee to review Maryland's limited formulary policy.

Pharmacy Security - This item was discussed under regulations.

Task Force on Automation - Jeanne Furman reported that she had been forwarded a letter from Georgia enquiring whether the Board had already or intended to license "robots", specifically "Envoy" for use in automated dispensing. She expressed the belief that the Board did not intend to license or authorize the use of specific machinery. The Board affirmed this position. Regulations will address the requirements for automated dispensing and the permit holder will be responsible for determining whether a specific type of automation meets those requirements.

Dr. Love reported that at the last meeting of the Practice Committee, held March 3, 1999 including discussions focusing on drug depots and outsourcing. Drug depot concerns primarily addressed delivery issues and the maintaining of patient confidentiality, evidence of tampering and the availability of pharmacist counseling when required by the patient picking up drugs from a depot.

With respect to outsourcing, the key issue in outsourcing continues to be whether the item is patient specific. Where this is the case and records are maintained appropriately, there was less of an issue, for example when the prescription is transmitted to the outsourcing pharmacy. However an ongoing business which does not fill per prescript would possibly be a manufacturer. Dr. Yee raised the subject of special packaging, specifically a prefilled syringe as a less expensive alternative to a minibag. Board members commented on the letter from last month from EMT Rx which concerned syringes, and concluded that as long as prescriptions were used, the EMT case seemed to comply with the law. The Board referred this matter for discussion at the next practice committee.

The next Practice Committee meeting will be held on April 7, 1999 at 4:30 P.M.

Budget Committee - Ms. Banks reported that the Department has requested the Board to look at its basic functions and define related needs, in part to anticipate potential difficulties and their avoidance in Y2K and to focus on efficiency and speed of licensing and outcomes of disciplinary matters.

The Maryland Board of Pharmacy Draft Public Minutes - March 17, 1999

Budget Committee Disciplinary summary of regulatory goals.

Mr. Rubin reported that with regard to consumer complaints, it is proposed that a form letter of acknowledgment of receipt of the complaint would be sent out within 14 business days. Mr. Lottier moved to accept this policy, of the letter of acknowledgment, seconded by Dr. Love and accepted.

Ms. Banks reported that the RFP for the media campaign is being treated as a new campaign, therefore we need to select vendor, and the RFP for the venter may be with the Office of Attorney General for review. Ms. Banks stated that it may be problematic to get the campaign moving before the end of this financial year, and that is unlikely that the funds could be disbursed by the end of the fiscal year, although she anticipated a May 15, 1999 start date for the media campaign.

Dr. Love and Board members discussed the Website for Board Members, which could included copies of pharmacy law.

Mr. Denoyer suggested we publish Title 12 and applicable regs in non-copyrighted electronic format to be available to the website of other organizations. He also suggested that the Division of State documents could publish such a limited book and opined that the estimated cost would be less than \$5 thousand dollars. Mr. Shciff asked whether MPHA may bid on the process, and was informed that it could be put up for bid.

Mr. Ballard questioned whether the Board had an additional contractual obligation to Michie, and Ms. Banks stated that she thought there was no contract for additional publication of any restrictions in a contratt.

Questions for the Board:

Health Services Plus- Mr. Denoyer reported that he had received a letter from this company enquiring whether drug deliveries for a physician could be delivered to an address other than that on the MD's medical or DEA license. After some discussion the Board reiterated the language of the current regulations, i.e. that only these two addresses were legitimate sites for delivery.

Newsletter re Y2K stockpiling- Laura Schneider is to attend a meeting sponsored by a trade association to dicuss allocations of drug supplies by manufacturers before Aprkil 2, 1999 and wil report back to the Board.

Ms. Levi asked what follow up the Board had completed regarding the Aromatherapy Apothecary at Touch the Earth on Charles Street in Baltimore. Mr. Denoyer reported that the apothecary was not providing any prescription drugs and consequently would not require a license so long as

The Maryland Board of Pharmacy Draft Public Minutes - March 17, 1999

the prefix “Aromatherapy” was always used whenever there was reference to the term “Apothecary”. Mr. Ades commented on a similar case in Bel Air called “patient first” which has the name pharmacy on the building.

Informational

Jeanne Furman reported on the matter of packaging medication doses for schoolchildren on field trips. Previously the Board had sanctioned placing a single dose of the medication in an envelope labeled with the student’s name, the name and strength of the medication, and the time for administration. After some discussion, the Board declined to ratify their prior letter and proposed that the parent obtain a spare, empty, labeled vial at the time that the prescription is dispensed. Ms. Putz indicated that Ritalin, as a schedule II drug would be labeled “Do Not Transfer”. This issue was not addressed by the Board.

Other Business- Dr. Love presented two other issues to the Board.

At present the code of Conduct has no language regarding a pharmacist’s right to refuse to dispense a prescription, based on the pharmacist’s moral or ethical beliefs.

RU486 will be available in the US by the fall of 1999. Language should be available before the drug is on the market. Mr. Ballard advised against delaying the Code of Conduct in order to add pertinent language due to the controversial subject matter which could jeopardize passage of the balance of the regulations. The Board concurred and no further action was proposed at this time.

Dr. Love also reported that Merck Medco is planning to provide M.D.S. with terminals in their offices for direct transmission of prescriptions to Merck pharmacies only. This is presently proscribed by Maryland law. Presently, Maryland laws cannot be applied to an out-of-state pharmacist unless he does harm in this state. Moved to refer the topic to the next National NABP meeting next month. Seconded the motion which was approved by the Board.

Stanton Ades

Meeting Adjourned at 11:15 a.m.

Respectfully Submitted,

W. Irving Lottier, Jr.
Secretary